

## **REMARKS**

### **A. Regarding the Amendments**

Upon entry of the amended claim set, claims 26 and 30 to 53 will be pending. Claims 4-9 and 14-17 were previously canceled. In the present Amendment, Claims 1 to 3, 10 to 13, 18 to 25 and 27, to 29 have been cancelled without prejudice or disclaimer. Applicant reserves the right to pursue the subject matter of the cancelled claims in a timely-filed continuation, continuation-in-part, or divisional application.

Claim 26, currently on file, has been amended to more clearly define the scope of protection being sought. New claims 30 to 53 have been added to claim additional embodiments of the present invention. Applicant asserts that no new matter has been added by way of these amendments. Support for the amendments and new claims can be found throughout the specification as filed and as outlined below.

Amended claim 26 and new claims 34 to 44 are directed to formulations comprising extracts derived from specified plants. Support for these claims can be found throughout the specification as filed, for example, at page 57 to 63, and in the Examples.

New claims 30 to 32, correspond to original claims 2, 3, and 7, and are supported throughout the specification as filed.

New claim 33 specifies that the glycol is butylene glycol or propylene glycol. Support for this claim can be found throughout the instant specification, for example, at page 19 (lines 2 and 3), and in the Examples.

New claim 45 specifies that the formulation comprises a moisturising agent. Support for this claim can be found throughout the instant specification, for example, at page 40 (line 27) to page 42 (line 14).

New claim 46 specifies that the formulation is formulated for topical or oral administration. Support for this claim can be found throughout the instant specification, for example, at page 40 (lines 11 to 15, and lines 21 to 26).

New claims 47 to 50, correspond in part to original claims 10 to 13, and are supported throughout the specification as filed, for example, at page 8 (lines 3 to 12), page 10 (lines 16 to 22) and page 46 (line 13) to page 48 (line 13).

New claims 51 to 53 specify that the dermatological formulation is administered orally or topically. Support for these claims can be found throughout the instant specification, for example, as outlined above for new claim 46.

## 1. Election

Applicant elects, with traverse, Group I drawn to a product. Applicant further elects, with traverse, the following species:

From "[t]he many different extracellular proteases in claims 1, 18, and 29": MMP 9.

From "[t]he many different cellular activities in claims 2 and 18": increase/stimulate collagen production.

From "[t]he many different plant extracts in claims 25 and 26": *Chenopodium quinoa*.

Applicant asserts that new claims 30 to 53 submitted herewith are drawn to formulations comprising plant extracts and methods of utilizing same and, therefore, should be examined with elected Group I.

## 2. Remarks

The claims currently pending stand restricted under 35 U.S.C. 121 and 372 into the following groups as defined by the Examiner at page 2 of the Office Action:

Group I, claims 1-3, 10-13 and 25-28, drawn to a product.

Group II, claims 18-24 and 29, drawn to a process of making the product.

The Examiner alleged that Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding technical features. The Examiner has stated that Cyr (US 2004/0175439) teaches the technical feature of plant extracts and compositions comprising extracellular protease inhibitors against extracellular proteases which degrade human tissue matrix and, therefore, there is no special technical feature in the application.

Applicant respectfully traverses the Examiner's restriction for the following reasons. Firstly, Applicant asserts that the currently pending claims relate to dermatological formulations comprising an effective amount of one or more plant extracts having MMP-1, MMP-2, MMP-3, MMP-9 and HLE extracellular protease inhibiting activity, that are capable of modulating one or more cellular activities in the skin. PCT Rule 13.2 states that in order to fulfill the requirement of unity of invention under Rule 13.1, there must be "a technical relationship among those inventions involving one or more of the same or corresponding special technical features." "Special technical features" are defined as "those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." In this regard, Applicant notes that Cyr does not disclose dermatological formulations comprising plant extracts capable of inhibiting one or more of MMP-1, MMP-2, MMP-3, MMP-9 and HLE nor does the

reference disclose formulations that modulate one or more cellular activities in the skin, as recited in the currently pending claims.

Secondly, Applicant asserts that the claims of Groups I and II should be examined together, as they meet the requirement under PCT Rule 13.1 and 13.2, and 37 CFR 1.475 for belonging to permissible combinations of different categories. In this regard, the Examiner is also directed to Section (e)(i) of Annex B of the PCT Administrative Instructions, which permits, for the purposes of determining unity of invention under Rule 13.2 “claims of different categories in the same international application: (i) in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of said product.” Applicant asserts that as the currently pending claims are directed to dermatological formulations comprising plant extracts and processes for identifying plant extracts suitable for the preparation of dermatological formulations, the claims should be examined together.

Thirdly, Applicant notes that the guidelines set forth in MPEP § 803 clearly indicate that there are two criteria for a proper requirement for restriction between patentably distinct inventions: (A) the inventions must be independent (see MPEP § 802.01, § 806.04, § 808.01) or distinct as claimed (see MPEP § 806.05 - § 806.05(i)); and (B) there must be a serious burden on the Examiner if restriction is required (see MPEP § 803.02, § 806.04(a) - § 806.04(i), § 808.01(a), and § 808.02). If the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.

Applicant asserts that the claims of Groups I and II are connected by a single, searchable unifying relationship as discussed above, *i.e.* all claims relate to dermatological formulations comprising a plant extract capable of modulating one or more cellular activities in the skin, and, in view of this single, searchable unifying relationship, Applicant asserts that the Examiner would not be seriously burdened by searching and examining the claims of Groups I and II in a single application.

In summary, Applicant asserts that not only has the requirement of unity of invention as defined under PCT Rule 13.1 and 13.2 been met in that the claims of Groups I and II share the same special technical features and belong to permissible combinations of different categories, as described above, but also that the claims of Group I and II are connected by a single, searchable unifying relationship and that the Examiner would not, therefore, be seriously burdened by searching and examining the subject matter of these groups in a single application. Accordingly, Applicants respectfully request withdrawal of the restriction of claims 1 to 3, 10 to 13 and 18 to 29.

The Examiner has further alleged that the application contains claims that are directed to more than one species of the generic invention. The Examiner has identified the species as follows:

The many different extracellular proteases in claims 1, 18, and 29

The many different cellular activities in claims 2 and 18

The many different plant extracts in claims 25 and 26

The Examiner has alleged that these species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The Applicant respectfully traverses the Examiner's further restriction. As discussed above, Applicant maintains that the pending claims are linked by a single, searchable unifying relationship, namely, a dermatological formulation comprising a plant extract capable of modulating one or more cellular activities in the skin, and can, therefore, be searched and examined in a single application without seriously burdening the Examiner.

Solely for the purpose of expediting the prosecution of the instant application, however, Applicant has cancelled claims 1 to 3, 10 to 13, 18 to 25 and 27 to 29, without prejudice or disclaimer. Applicant elects, with traverse, Group I, consisting of amended claim 26 and new claims 30 to 51, which are drawn to dermatological formulations and methods of utilizing same. Applicant respectfully submits that not only are the claims submitted herewith linked by a single searchable unifying relationship as noted above, but also that the claims belong to permissible categories of claims as identified in Section (e)(i) of Annex B of the PCT Administrative Instructions as noted above.

Applicant further elects, with traverse, the species: MMP-9, increase/stimulate collagen production and *Chenopodium quinoa*. In this regard, Applicant notes that the claims as amended recite a limited group of eleven specifically named plants from which the extracts are derived. As such, Applicant asserts there is no serious burden on the Examiner to search and examine all of the recited extracts in a single application. Applicant further asserts that it would be overly limiting to restrict the search and examination of the submitted claims to a single cellular activity given that the extracts are already defined as being capable of modulating the cellular activity of a specific cell type (*i.e.* skin). Similarly, Applicant submits that the extracts are defined as being capable of inhibiting a particular type of protease (*i.e.* extracellular) and that limiting the search and examination to a single enzyme would be unduly restrictive.

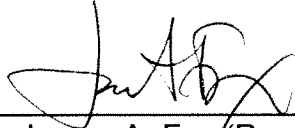
### **CONCLUSION**

Applicants respectfully request consideration and allowance of all claims. An early indication of their allowance is earnestly requested. The Examiner is invited to contact the undersigned attorney at the telephone number indicated below should he find that there are any further issues outstanding.

Fees for a two-month extension of time are believed to be due at this time. Please charge any fees, including fees for the extension of time, and any additional extension of time if needed, or credit overpayment to Deposit Account No. **08-1641** referencing Attorney's Docket No. **41313-1004**.

Respectfully submitted,

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